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**AUG 11 2008**

In re Application of	:	
Anderson et al.	:	
Application No. 09/911,703	:	LETTER REGARDING
Filed: July 25, 2001	:	PATENT TERM ADJUSTMENT
Attorney Docket No. 27693-01008	:	
Title: ANTI-CD20 ANTIBODIES	:	

This is a decision on the "LETTER REGARDING PATENT TERM ADJUSTMENT," filed February 15, 2008. Applicant requests that the initial determination of patent term adjustment at the time of mailing of the notice of allowance be corrected from seven hundred and two (702) days to six hundred and three (603) days.

The request for reconsideration of the patent term adjustment is **GRANTED TO THE EXTENT INDICATED HEREIN.**

The Office has updated the PAIR screen to reflect that the correct Patent Term Adjustment (PTA) determination at the time of the mailing of the Notice of Allowance is five hundred twenty-two (522) days. A copy of the updated PAIR screen, showing the correct determination, is enclosed.

On January 29, 2008, the Office mailed the Determination of Patent Term Adjustment under 35 U.S.C. 154(b) in the above-identified application. The Notice stated that the patent term adjustment to date is 702 days. The instant letter was timely filed<sup>1</sup> on or before payment of the issue fee. Applicant sets

<sup>1</sup> PALM records indicate that the issue fee was paid on February 15, 2008.

forth the following basis for recalculation of the patent term adjustment:

1. Applicant discloses that a period of reduction should be entered for the interval between three-months after the February 27, 2004 submission of a non-compliant sequence listing and the amendment filed on December 15, 2004 (e.g. May 27, 2004 to December 15, 2004 or 202 days).
2. Applicant discloses that given that the compliant sequence listing was not filed until December 15, 2004, the time for the Office to act on the response to the sequence letter under 1.703(a)(2) should run from December 15, 2004, and thus, entry of a period of adjustment of 21 days for Office delay is not warranted.
3. Applicant asserts that an interval between 4 months after the sequence listing of August 12, 2005 and the mailing of the December 29, 2006 Office action should constitute Office delay.
4. Applicant discloses that a period of reduction of 81 days should be entered for applicant delay for the IDS filed November 1, 2005.

Applicant states that any patent that issues from this application is subject to a terminal disclaimer.

Applicant's arguments have been considered and found persuasive to the extent indicated herein.

Applicant is correct that the incorrect periods were entered with respect to their delay in filing a compliant reply on December 15, 2004. Applicant is correct that a period of reduction for the entire interval and not separate periods of 58, 61 and 28 days should have been entered. However, applicant has not correctly calculated this period. The period is 266 days, not 202 days.

Pursuant to 37 C.F.R. § 1.704(c)(7), the submission of a reply having an omission (§1.135(c)) is a failure to engage in reasonable efforts to conclude prosecution, and the period of adjustment set forth in Rule 1.703 shall be reduced by the

number of days, if any, beginning<sup>2</sup> on the day after the date the reply having an omission was filed and ending on the date that the reply or other paper correcting the omission was filed. The period of reduction begins the day after the reply containing an omission was actually filed and not the day after the three month due date for the reply. In this instance, on February 27, 2004, the Office mailed a Notice to Comply with Sequence Requirements. On March 24, 2004, applicant filed a response. On March 30, 2004, applicant filed a further response to correct an omission in the response filed March 24, 2004. By Notice to Comply mailed June 17, 2004, applicant was advised that the response as filed March 30, 2004 contained an omission. A sequence listing was filed on November 17, 2004. However, it contained errors. It is undisputed that a sequence listing correcting the errors was not filed until December 15, 2004. Thus, the period of reduction pursuant to 37 CFR 1.704(c)(7) begins on March 25, 2004, the day after the first reply containing an omission was filed, and ends on December 15, 2004, the date the omission was corrected.

The response submitted on March 24, 2004 contained an omission that was later corrected via the submission of a response on December 15, 2004. This constitutes a delay of 266 days. Accordingly, the periods of reduction of 58, 61 and 28 days for applicant delay are being removed and a period of reduction of 266 days is being entered.

However, applicant is incorrect that entry of a period of adjustment of 21 days for Office delay in association with the mailing of the non-final Office action on April 7, 2005 is incorrect. Pursuant to 37 C.F.R. § 1.702(a)(2), the Office is required to respond to a reply under 35 U.S.C. 132 not later than four months after the date on which the reply was filed. The Office did not take action in response within four months (e.g. mail an action under 37 CFR 1.135(c)). A non-final Office action was mailed on April 7, 2005, four months and 21 days later. The period of adjustment of 21 days for Office delay is being retained.

However, applicant is correct that a period of adjustment pursuant to 37 C.F.R. § 1.702(a)(2) should be entered for Office delay in taking action in response to the amendment filed August

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<sup>2</sup> When a period is indicated (in 37 CFR 1.703 or 1.704) as "beginning" on a particular day, that day is included in the period, in that such day is "day one" of the period and not "day zero." For example, a period beginning on April 1 and ending on April 10 is ten (and not nine) days in length. See MPEP 2731.

12, 2005. An Office communication was mailed on November 2, 2005, indicating that the submission filed August 12, 2005 contained an omission. A response was submitted on December 2, 2005, asserting that the November 2, 2005 Office communication was issued in error and should be vacated. In response, the Office mailed a communication on February 28, 2006, which indicated that this submission was not fully responsive. A petition was filed on April 28, 2006, directed towards the propriety of the assertion that the submission of August 12, 2005 contained an omission. This petition was granted via the mailing of a decision on July 26, 2006, which vacated the mailings of November 2, 2005 and February 28, 2006. A final Office action was next mailed on December 29, 2006.

The Office entered a period of adjustment of 271 days for Office delay in taking action in response to applicant's response filed December 2, 2005. Given the petition decision, for purposes of calculating patent term adjustment, the mailing of the Office action on December 29, 2006 is used as the date the Office took action in response to the reply filed August 12, 2005. The Office was required to respond to the August 12, 2005 submission no later than December 12, 2005, and the communication of December 29, 2006 is four months and 382 days after the receipt of the amendment. See 37 C.F.R. 1.703(a)(2). The period of adjustment of 271 days is being removed and a period of adjustment of 382 days is being entered.

Moreover, applicant is correct that a period of reduction of 81 days should be entered for the supplemental Information Disclosure Statement (IDS) filed on November 1, 2005. Pursuant to 37 C.F.R. § 1.704(c)(8), submission of a supplemental reply or other paper, other than a supplemental reply or other paper expressly requested by the examiner, after a reply has been filed, is a failure to engage. In which case the period of adjustment set forth in § 1.703 shall be reduced by the number of days, if any, beginning on the day after the date the initial reply was filed and ending on the date that the supplemental reply or other such paper was filed. In this instance, after the filing of a response on August 12, 2005, on November 1, 2005, applicant filed an IDS. The record supports a conclusion that the IDS was not expressly requested by the examiner and did not include a 1.704(d) statement. Accordingly, the patent term adjustment should have been reduced by 81 days, the number of days beginning on the day after the date the initial reply was

filed, August 13, 2005, and ending on the date that the IDS was filed, November 1, 2005.

Regarding the paper filed on February 16, 2007 and the subsequently submitted petition of March 29, 2007 that was accompanied by a complete response on the merits, it is noted that the Office properly did not assign a reduction based on either the request for reconsideration that was filed prior to the response or the petition that was filed with the response. No reduction is warranted for papers filed prior to or with the proper response to a final Office action. Further, the reply under 37 CFR 1.116 was in compliance with 1.113(c) and was filed within the three month period set forth in 37 CFR 1.704(b).

However, a review of the record reveals the basis for entry of a further period of reduction. After filing the response on March 29, 2007 on June 28, 2007, applicant filed a Notice of Appeal. The Notice of Appeal was not requested by the examiner. Pursuant to 37 CFR 1.704(c)(8), a period of reduction of 91 days is being entered.

The other periods of delay are not at issue.

The proper period of adjustment for Office delay at the time of the mailing of the notice of allowance is 996 (366 + 21 + 382 + 227) days. The proper period of reduction at the time of mailing of the notice of allowance is 474 (266 + 36 + 81 + 91) days.

In view thereof, the correct patent term adjustment at the time of the mailing of the notice of allowance is 522 (996 - 474) days.

The application is being forwarded to the Office of Data Management for issuance of the application. The patent term adjustment indicated on the patent (as shown on the Issue Notification mailed about three weeks prior to patent issuance) will include any additional adjustment accrued both for Office delay in issuing the patent more than four months after payment of the issue fee and satisfaction of all outstanding requirements, and for the Office taking in excess of three years to issue the patent (to the extent that the three-year period does not overlap with periods already accorded).

Telephone inquiries specific to this matter should be directed to Senior Attorney Paul Shanowski at (571) 272-3225.

A handwritten signature in black ink, appearing to read "Nancy Johnson". The signature is fluid and cursive, with the first name "Nancy" being more prominent than the last name "Johnson".

Nancy Johnson  
Senior Petitions Attorney  
Office of Petitions

Enclosure: Copy of Revised PTA calculation